

REMARKS

Claims 27-32 and 48-53 were examined. Claim 27 is amended. Claims 27-32 and 48-53 remain in the Application.

The Patent Office rejects claims 51 and 52 under 35 U.S.C. §112, first paragraph. The Patent Office rejects claims 27-28, 31-32, and 48 under 35 U.S.C. §103(a). Finally, the Patent Office objects to claims 27-30, 49-50, and 53 as dependent upon a rejected base claim, but otherwise finds such claims allowable over the prior art of record. Applicant respectfully requests reconsideration of the pending claims in view of the above amendment and the following remarks.

A. 35 U.S.C. §112, First Paragraph: Rejection of Claims 51-52

The Patent Office rejects claims 51-52 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Patent Office believes the application does not describe that delivering comprises delivering the treatment agent before the barrier or after the barrier. Applicant believes the application fully supports the claims. For example, at page 23, lines 16-25 the application provides:

The barrier and agent are presented to the target tissue site in a time-varied manner, wherein the barrier is provided a different time from the introduction of the agent. However, it is essential that the agent and barrier both be present at or near the target tissue during at least partially overlapping times. The process may include successive contact of agent with the target site followed by contact with the barrier to the target surface. In another embodiment, first the barrier and then the agent is sequentially introduced. The gap of time between contacting the agent and barrier is typically very short, especially where the dispensing of agent precedes the barrier. A time gap from 5 to 10 minutes is common and more usually 1 to 2 minutes. The time gap is based on clinical factors familiar to one skilled in the art.

Claims 51 and 52 each depend from claim 27. Claim 27 states that a treatment and a barrier are delivered to a tissue such that the treatment agent and the barrier are present at or near the tissue during at least partially overlapping times. Claims 51 and

52 further describe the order of delivery. The quoted language from the application clearly supports successive delivery.

Applicant respectfully requests the Patent Office withdraw the rejection of claims 51-52 under 35 U.S.C. §112, first paragraph.

B. 35 U.S.C. §103(a): Rejection of Claims 27-28, 31-32 & 48

The Patent Office rejects claims 27-28, 31-32, and 48 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,458,387 issued to Scott, et al. ("Scott"). Scott is cited for disclosing a sustained release composition, including a macromolecule and a complexing agent (see col. 5, lines 25-34) where the complexing agent is capable of ionic interaction with a therapeutic agent (col. 5, lines 55-67).

Claims 27, 31 and 32 describe a method comprising successively delivering a treatment agent and a barrier to a tissue such that the treatment agent and the barrier are present at or near the tissue during at least partially overlapping times.

Scott does not disclose successive delivery of a complexing agent and a therapeutic agent. Scott describes sustained-released micro spheres. Accordingly, the composition necessarily includes the complexing agent and the therapeutic agent. There is no motivation to deliver these agents in a successive manner (*i.e.*, one before the other). Claim 28 describes a method including delivering a treatment agent to a tissue, the treatment agent with a barrier having a binding member and a delivery carrier. The binding member has a property adapted to couple to a surface of the tissue. The binding member is a counter ion of an ionic member on the surface of the tissue for attachment of the binding member.

As noted by the Patent Office, Scott discloses a macromolecule including a complexing agent and a therapeutic agent. The complexing agent may be an ionic complexing agent capable of ionic interaction with the therapeutic agent. See col. 5, lines 54-56. Scott does not teach that its complexing agent is a counter ion of an ionic member on the surface of a tissue. Scott is directed at an interaction between a complexing agent and a therapeutic agent to form the sustained-release composition. Claim 28, on the other hand, is directed at hindering transport of a treatment agent way

from tissue by the presence of a barrier that is attached to the tissue. Because, Scott does not teach or provide any motivation or prediction for delivering a treatment agent within a barrier having a binding member that is a counter ion of an ionic member on the surface of a tissue, claim 28 is not obvious.

Applicant respectfully requests that the Patent Office withdraw the rejection of claims 27-28, 31-32, and 48 under 35 U.S.C. §103(a).

C. Objection to Claims 29-30, 49-50 & 53

The Patent Office objects to claims 29-30, 49-50, and 53 as dependent upon a rejected base claim, but otherwise finds such claims allowable over the prior art of record. As noted above, Applicant believes the rejected claims are allowable and therefore so are the objected to claims. Applicant respectfully requests that the Patent Office withdraw the rejection to claims 29-30, 49-50, and 53.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: _____

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I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

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